The Reg Map®

Informal Rulemaking

Experts in drafting rulemaking documents and preparing supporting analyses

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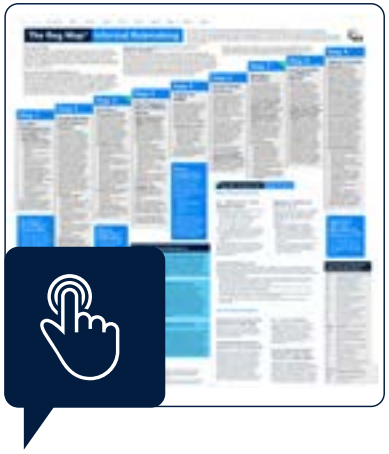

Full-size map

The Reg Map® Informal Rulemaking

What is the Reg Map?
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Must all rulemakings follow all Reg Map steps?
In a typical case, a rulemaking action would proceed from Step 1 to Step 9, including OMB review at the proposed and final stages for certain kinds of significant regulatory actions, per E.O. 12866. As the Reg Map shows, however, Congress has exempted some rulemaking actions from APA notice requirements. In addition, when stakeholders have challenged regulatory actions, courts have interpreted APA requirements over time, influencing how agencies carry out "informal" rulemaking procedures at a practical level, some of which is explained in the Reg Map.

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Step 1

Consider Initiating Events

- **Laws enacted by Congress**
- **Court decisions**
- **Agency initiatives from various sources, including:**
  - Agency plans and priorities
  - New data, technologies, or research
  - Patterns of accidents or violations
  - Public comments on RFIs
  - Retrospective analyses of existing regulations
  - Recommendations from the President, OMB, other agencies, congressional committees, federal advisory committees, states, or external groups
  - Changes in the regulated community
  - Petitions for rulemaking, including petitions for reconsideration

See www.regulations.gov and www.reginfo.gov for intended regulatory and deregulatory actions and for other resources.

Revising or Rescinding an Existing Rule

Agencies seeking to modify or repeal a rule must follow the same informal rulemaking process requirements as they would for promulgating a new rule. See APA sec. 551(5) (5 U.S.C. 551(5)).

Reducing Regulatory Burden

Several administrations have undertaken efforts to reduce regulatory burdens by identifying and eliminating regulations that no longer serve their intended purposes or impose costs that cannot be justified. As reducing regulatory burden is an evolving topic, those interested should monitor the FAQs/Related Resources page of OIRA's website, as additional executive directives on this subject are likely in the future.

Step 2

Decide Whether Public Notice Is Needed

Unless other exemptions apply, APA sec. 553 requires public notice and comment to propose a rule or a showing of "good cause"—an agency demonstration that notice and comment are "impracticable, unnecessary, or contrary to the public interest" (omit Steps 3 through 6). Generally, this exemption applies only to cases where: the rule is a minor determination in which the public is not interested or that involves little to no agency discretion; advance notice would defeat the regulatory objective; immediate action is necessary to reduce imminent harm to people or property; or Congress implicitly waives notice-and-comment requirements.

"Good cause" options:

- Emergency rules
- Interim final rules (omit Steps 3 through 6 but provide comment period and final rule after Step 9)
- Rules that codify statutory language where agency has no discretion to change the provision
- Direct final rules (streamlined process for non-controversial rules; must be withdrawn if opposed)
- Technical corrections

Other exemptions include interpretive rules; general policy statements; agency rules of procedure, organization, or practice; rules involving a military or foreign-affairs function of the United States; or matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts (omit Steps 3 through 6).

If no exemptions apply, options for notice and comment include:

- NPRM (proposes specific provisions with rationale and seeks comment)
- ANPRM (seeks comments and data to help develop a proposed rule)

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Develop a Proposed Rule

An NPRM proposes to add, revise, remove, or re-designate CFR provisions, and it must consist of a description or statement of the proposed regulatory text and a preamble to inform a non-expert reader of the proposal's basis and purpose. See 1 CFR 18.12.

The NPRM must explain:

- Legal basis: The statutory authority to issue rules for the regulated entities and the subject area
- Proposed provisions: A presentation of the proposed rule text or a description of the issues
- Rationale for each proposed provision: An explanation of why a rule is needed; what it would accomplish; and what data, research, analyses, and assumptions were used to develop the rule

Rule preamble should discuss:

- Regulatory background and history
- Alternatives the agency is considering
- Analyses describing compliance with applicable statutes or executive orders

Analyses begun in Step 3 must be finalized in Step 7.

What Is Negotiated Rulemaking?

A negotiated rulemaking allows agency staff and stakeholders, or interested and affected parties, to develop a proposed rule together, facilitated by a mediator. See 5 U.S.C. 561-570.

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Send Proposed Rule to OMB for Review

OMB will review any rule an agency or OIRA considers "significant" under E.O. 12866. See E.O. 12866 sec. 6. (OIRA is the OMB office responsible for coordinating executive branch review of agency rulemaking documents and reviewing agency ICRs under the PRA.)

- 10-day OMB review for agency's preliminary "significant" determination
- 90-day OMB review for rule, assessments, and analyses (120 days if director of OMB grants extension)
- OIRA may waive review
- Agency head may request extension

An agency must submit with the rule an RIA (i.e., cost-benefit assessment) for any significant regulatory action.

Interagency review coordination: OMB may circulate an NPRM to other agencies interested in the content.

OMB will invite the issuing agency to meetings requested by the public to discuss regulatory actions under review per E.O. 12866 sec. 6(b)(4).

See www.reginfo.gov/public to keep up with OMB review actions and for other resources.

Step 5

Publish the NPRM

An agency must publish "either the terms or substance of the proposed rule or a description of the subjects and issues involved" in the *Federal Register*, the official daily publication for federal agency actions. See APA sec. 553(b).

The NPRM also must include:

- Statement of the time, place, and nature of public rulemaking proceedings
- Reference to the legal authority under which the rule is proposed
- Regulation Identifier Number

See www.federalregister.gov for the daily *Federal Register* and for other resources.

What Is Incorporation by Reference?

With the approval of the Director of the *Federal Register*, an agency may incorporate material into rules by simply referencing it. Such material must be:

- Published
- Reasonably available to and usable by affected individuals
- Not produced by the agency

Congress authorized this process to reduce the volume of language published in the *Federal Register* and CFR. The legal effect is that the referenced material is treated as if it were newly published in the *Federal Register*.

Step 6

Analyze Public Comments

An agency must give the public a meaningful opportunity to submit written comments, in paper or electronic form, and it must consider all "relevant matter presented." See APA sec. 553(c). E.O. 12866 recommends a comment period of at least 60 days.

The E-Government Act of 2002 requires agencies to provide for electronic filing of public comments and make dockets available online (Pub. L. 107-347 sec. 206(d)). See www.regulations.gov, the online portal for submitting public comments.

Courts have interpreted the APA requirements noted above to mean that **agencies must provide responses to significant issues raised in the comments**. Significant issues are relevant points that, if adopted, would require a change to the agency's proposed rule.

Step 7 *

Develop a Final Rule

A final rule presents the CFR provisions adopted and must incorporate into the preamble a concise general statement of the basis and purpose for the agency decision. See APA sec. 553(c). **Final rule choices must not be "arbitrary and capricious" (i.e., fail to provide a rational basis for the decision).** See 5 U.S.C. 706. **A final rule must be within the scope and a "logical outgrowth" of the proposed rule.** A final rule can be substantially different from the NPRM so long as the agency provided adequate notice to the public of the possibility for changes of the type that were adopted.

Final rule documents:

- Explain the provisions adopted and the reasons for the agency's decisions, including a discussion of changes from the NPRM
- Discuss and respond to significant public comments
- Update and finalize analyses begun in Step 3
- Set an effective date and any applicable compliance date (see Step 9)

Step 8

Send Final Rule to OMB for Review

OMB will review any rule deemed "significant" under E.O. 12866. Agencies must ensure that a rulemaking schedule accounts for at least a 90-day OMB review period for significant rules. OIRA may permit a shorter period of review in exigent circumstances. **The agency must revise the regulatory package to address OMB concerns and respond to any interagency review comments.** E.O. 12866 also includes requirements relating to OIRA communications with individuals outside the executive branch about the substance of a regulatory action under review. After publication of the regulatory action in the *Federal Register*, an agency must identify for the public the substantive changes between the draft submitted to OIRA for review and the action subsequently announced plus the changes it made at OMB's recommendation or suggestion (E.O. 12866 sec. 6(a)(3)(E)).

Step 9

Publish Final Rule

Effective date: The APA specifies that agency rules generally may not take effect until at least 30 days after publication in the *Federal Register*, except for a substantive rule that grants an exemption or relieves a restriction or for other "good cause." See APA sec. 553(d). Agencies can set a more delayed *effective date* (date on which regulatory changes are implemented in CFR) for some or all rule provisions and can set an even more delayed *compliance date* (date by which regulated persons must comply) for some or all of the rule requirements.

Congressional Review Act (5 U.S.C. ch. 8): Under the CRA, before most final rules can take effect, an agency must submit them and supporting information to the House, the Senate, and the GAO. Rules defined as "major" under the CRA may not take effect for at least 60 days (30 days for non-major rules), with exceptions in some cases.

Bases for legal challenges include claims that the agency:

- Had no statutory authority to issue the rule
- Failed to address statutory criteria for issuing rules or considered factors not allowed by the statute
- Provided inadequate notice (e.g., final rule not a "logical outgrowth" of the proposal, no NPRM with inadequate "good cause")
- Failed to consider public comments
- Reached an "arbitrary and capricious" decision (i.e., provided no rational basis for the action) (see 5 U.S.C. 706)

See www.ecfr.gov for the latest unofficial version of the CFR.

Regulations with Legal Effect Must Be Published in CFR

The Federal Register Act at 44 U.S.C. 1510 (implemented at 1 CFR 8.1) requires regulations that have general applicability and legal effect to be published in the CFR.

Frequently Asked Questions

How Should Agencies Draft Rulemaking Documents?

E.O. 12866 (Regulatory Planning and Review), E.O. 12988 (Civil Justice Reform), and the Presidential Memorandum on Plain Language (63 FR 31885) all direct agencies to use plain language in drafting rulemaking documents. Rulemaking documents also must conform to publication requirements in the OFR regulations (1 CFR chs. I and II). The OFR provides additional drafting guidance in its Document Drafting Handbook.

What Rules Are Agencies Planning to Issue?

A Unified Agenda (formally the Unified Agenda of Federal Regulatory and Deregulatory Actions) is published in the *Federal Register* in the spring and fall of each year, as required by E.O. 12866. The Unified Agenda provides information concerning agency rules under development and review, including the Regulatory Plan (showing the most important significant regulatory actions agencies plan to take – fall only) and the Regulatory Flexibility Agenda (describing actions likely to result in SEISNOSE – spring and fall). The most recent Unified Agenda can be accessed on www.reginfo.gov. The E.O. 12866 requirements to list regulatory actions in the Unified Agenda apply to independent agencies as well as executive agencies.

What Is in a Rulemaking Record?

To facilitate possible judicial review, an agency must maintain an administrative record or "docket" throughout the rulemaking process, which should include all documents and materials directly or indirectly considered by the agency in developing the rule, including:

- Any research, data, analyses, or other sources the agency used and relied on to support the agency action
- All public comments and supporting materials
- Transcripts/notes or recordings from public meetings or hearings
- Notes/documentation of meetings with outside parties
- OMB's comments on any proposed ICR under 5 CFR 1320.11(c)
- All assessments and analyses submitted to OMB/OIRA under E.O. 12866 sec. 6(a)(3)
- All other required analyses (e.g., any regulatory flexibility analyses)

What Is the Difference Between a Rule and a Regulation?

Technically, these terms are usually interchangeable. See APA sec. 551(4); 1 CFR 1.1; E.O. 12866 sec. 3(d). But colloquially, they do not always have the same meaning. People often use the word "rule" to reference a specific NPRM or final rule (i.e., the *Federal Register* document that proposed or finalized a specific set of regulations). With that use of the term, "rule" can refer to either the preamble explanatory text or the regulatory text or both. This use of the term "rule" is not interchangeable with "regulation" because, for example, proposed regulatory text is not yet a regulation, and final rule preamble language is never a regulation.

* Specific Analyses for Steps 3 and 7

Most Frequent Analyses

E.O. 12866 and E.O. 13563, Regulatory Review

RIA required for "significant regulatory actions," which include those that would:

- Have a $100 million or more annual effect on the economy (in current dollars)
- Raise novel legal or policy issues
- Have other significant impacts

If the annual effect is $100 million or more, the rule is "economically significant" and requires:

- Cost-benefit analysis of policy alternatives
- Quantified and monetized costs and benefits

If a rule is significant but the annual effect is less than $100 million, an agency must analyze costs and benefits of the selected approach. OIRA may also require assessment of policy alternatives.

Regulatory Flexibility Act (5 U.S.C. ch. 6)

Applies to rules that may have a "significant economic impact on a substantial number of small entities" (SEISNOSE), if APA or other statutory notice and comment is required.

An agency must analyze small-entity impacts and mitigate them if possible.

- If there is a SEISNOSE, an agency must estimate the number of small entities affected and the potential effects on them and consider alternatives to reduce the impacts
- If there is no SEISNOSE, the agency may certify as such and provide the basis for the certification – this certification is subject to judicial review

Paperwork Reduction Act

Applies to any agency "collection of information" imposed on 10 or more people and requires submitting an ICR to OMB for approval, which must detail the need for, use, burdens (time and costs), and methodology of the information collection. An RIA must reflect any changing information collection burdens in the rule.

- A collection of information occurs when an agency requires recordkeeping *or* obtains, solicits, or requires the disclosure to third parties of information, regardless of form or format (e.g., reporting requirements, application forms, surveys)
- Public meetings and *Federal Register* solicitations for public comment are not collections of information under the PRA (see 5 CFR 1320.3(h))
- The PRA applies broadly and is not limited to information collections in regulatory provisions – non-rule collections of information also must receive approval
- At least every 3 years, an agency must update, and OMB must approve, any collection of information

Less Frequent Analyses

National Environmental Policy Act (42 U.S.C. 4321-4347)

Analysis of a rule's environmental impacts required if the rule is a major federal action that could significantly affect the quality of the human environment.

Unfunded Mandates Reform Act (2 U.S.C. chs. 17A and 25)

Applies if the rule would impose a federal mandate that may result in the "expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year." Impact statement must include an analysis of the costs and benefits and a description of agency consultations with state, local, or tribal governments. Note that the UMRA does not apply to independent regulatory agencies.

E.O. 13132, Federalism

Impact statement required if the rule has federalism implications (e.g., potential preemption of state law) or would impose unreimbursed costs on state or local governments. Analysis must describe consultations with state and local officials, including the agency's response to their concerns.

Privacy Impact Assessment (E-Government Act, Pub. L. 107-347 sec. 208(b) (2002))

Applies if the rule involves collection, maintenance, or dissemination of identifying information "permitting the physical or online contacting of a specific individual" by an agency. The impact assessment must describe several aspects of the information collection, including the type of information, with whom it will be shared, and how it will be secured.

Other Potential Analyses

- Trade Agreements Act (19 U.S.C. 2531-2533)
- National Technology Transfer and Advancement Act (15 U.S.C. 272 note)
- Assessment of Federal Regulations and Policies on Families (Omnibus Appropriations Act 1999, Pub. L. 105-277 sec. 654 (1998))
- E.O. 12630, Government Actions and Interference with Constitutionally Protected Property Rights
- E.O. 12988, Civil Justice Reform
- E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks

E.O. 13175, Consultation and Coordination with Indian Tribal Governments E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

- Program statutes, executive orders, and agency regulations or policies may impose other analytical requirements

Frequently Used Rulemaking Terms and Abbreviations

ANPRM	Advance Notice of Proposed Rulemaking
APA	Administrative Procedure Act
CFR	Code of Federal Regulations
CRA	Congressional Review Act
DDH	Document Drafting Handbook
E.O.	Executive Order
FDMS	Federal Docket Management System
FOIA	Freedom of Information Act
FR	*Federal Register*
GAO	Government Accountability Office
IBR	Incorporation by Reference
ICR	Information Collection Request
IFR	Interim Final Rule
NegReg or RegNeg	Negotiated Rulemaking or Regulatory Negotiation
NPRM	Notice of Proposed Rulemaking
OFR	Office of the Federal Register
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
PRA	Paperwork Reduction Act
RFA	Regulatory Flexibility Act
RFI	Request for Information
RIA	Regulatory Impact Analysis/Assessment
RIN	Regulation Identifier Number
SEISNOSE or SISNOSE	Significant economic impact on a substantial number of small entities
UMRA	Unfunded Mandates Reform Act
U.S.C.	United States Code

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Effective date: The APA specifies that agency rules generally may not take effect until at least 30 days after publication in the *Federal Register*, except for a substantive rule that grants an exemption or relieves a restriction or for other "good cause." See APA sec. 553(d). Agencies can set a more delayed *effective date* (date on which regulatory changes are implemented in CFR) for some or all rule provisions and can set an even more delayed *compliance date* (date by which regulated persons must comply) for some or all of the rule requirements.

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E.O. 12866 (Regulatory Planning and Review), E.O. 12988 (Civil Justice Reform), and the Presidential Memorandum on Plain Language (63 FR 31885) all direct agencies to use plain language in drafting rulemaking documents. Rulemaking documents also must conform to publication requirements in the OFR regulations (1 CFR chs. I and II). The OFR provides additional drafting guidance in its Document Drafting Handbook.

What Rules Are Agencies Planning to Issue?

A Unified Agenda (formally the Unified Agenda of Federal Regulatory and Deregulatory Actions) is published in the *Federal Register* in the spring and fall of each year, as required by E.O. 12866. The Unified Agenda provides information concerning agency rules under development and review, including the Regulatory Plan (showing the most important significant regulatory actions agencies plan to take – fall only) and the Regulatory Flexibility Agenda (describing actions likely to result in SEISNOSE – spring and fall). The most recent Unified Agenda can be accessed on www.reginfo.gov. The E.O. 12866 requirements to list regulatory actions in the Unified Agenda apply to independent agencies as well as executive agencies.

What Is the Difference Between a Rule and a Regulation?

Technically, these terms are usually interchangeable. See APA sec. 551(4); 1 CFR 1.1; E.O. 12866 sec. 3(d). But colloquially, they do not always have the same meaning. People often use the word "rule" to reference a specific NPRM or final rule (i.e., the *Federal Register* document that proposed or finalized a specific set of regulations). With that use of the term, "rule" can refer to either the preamble explanatory text or the regulatory text or both. This use of the term "rule" is not interchangeable with "regulation" because, for example, proposed regulatory text is not yet a regulation, and final rule preamble language is never a regulation.

What Is in a Rulemaking Record?

To facilitate possible judicial review, an agency must maintain an administrative record or "docket" throughout the rulemaking process, which should include all documents and materials directly or indirectly considered by the agency in developing the rule, including:

- Any research, data, analyses, or other sources the agency used and relied on to support the agency action
- All public comments and supporting materials
- Transcripts/notes or recordings from public meetings or hearings
- Notes/documentation of meetings with outside parties
- OMB's comments on any proposed ICR under 5 CFR 1320.11(c)
- All assessments and analyses submitted to OMB/OIRA under E.O. 12866 sec. 6(a)(3)
- All other required analyses (e.g., any regulatory flexibility analyses)

Specific Analyses for Steps 3 and 7

Most Frequent Analyses

E.O. 12866 and E.O. 13563, Regulatory Review

RIA required for "significant regulatory actions," which include those that would:

- Have a $100 million or more annual effect on the economy (in current dollars)
- Raise novel legal or policy issues
- Have other significant impacts

If the annual effect is $100 million or more, the rule is "economically significant" and requires:

- Cost-benefit analysis of policy alternatives
- Quantified and monetized costs and benefits

If a rule is significant but the annual effect is less than $100 million, an agency must analyze costs and benefits of the selected approach. OIRA may also require assessment of policy alternatives.

Regulatory Flexibility Act (5 U.S.C. ch. 6)

Applies to rules that may have a "significant economic impact on a substantial number of small entities" (SEISNOSE), if APA or other statutory notice and comment is required.
An agency must analyze small-entity impacts and mitigate them if possible.

- If there is a SEISNOSE, an agency must estimate the number of small entities affected and the potential effects on them and consider alternatives to reduce the impacts
- If there is no SEISNOSE, the agency may certify as such and provide the basis for the certification – this certification is subject to judicial review

Paperwork Reduction Act

Applies to any agency "collection of information" imposed on 10 or more people and requires submitting an ICR to OMB for approval, which must detail the need for, use, burdens (time and costs), and methodology of the information collection. An RIA must reflect any changing information collection burdens in the rule.

- A collection of information occurs when an agency requires recordkeeping *or* obtains, solicits, or requires the disclosure to third parties of information, regardless of form or format (e.g., reporting requirements, application forms, surveys)
- Public meetings and *Federal Register* solicitations for public comment are not collections of information under the PRA (see 5 CFR 1320.3(h))
- The PRA applies broadly and is not limited to information collections in regulatory provisions – non-rule collections of information also must receive approval
- At least every 3 years, an agency must update, and OMB must approve, any collection of information

* Specific Analyses for Steps 3 and 7

Less Frequent Analyses

National Environmental Policy Act (42 U.S.C. 4321-4347)

Analysis of a rule's environmental impacts required if the rule is a major federal action that could significantly affect the quality of the human environment.

Unfunded Mandates Reform Act (2 U.S.C. chs. 17A and 25)

Applies if the rule would impose a federal mandate that may result in the "expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year." Impact statement must include an analysis of the costs and benefits and a description of agency consultations with state, local, or tribal governments. Note that the UMRA does not apply to independent regulatory agencies.

E.O. 13132, Federalism

Impact statement required if the rule has federalism implications (e.g., potential preemption of state law) or would impose unreimbursed costs on state or local governments. Analysis must describe consultations with state and local officials, including the agency's response to their concerns.

Privacy Impact Assessment (E-Government Act, Pub. L. 107-347 sec. 208(b) (2002))

Applies if the rule involves collection, maintenance, or dissemination of identifying information "permitting the physical or online contacting of a specific individual" by an agency. The impact assessment must describe several aspects of the information collection, including the type of information, with whom it will be shared, and how it will be secured.

Specific Analyses for Steps 3 and 7

Other Potential Analyses

- Trade Agreements Act (19 U.S.C. 2531-2533)
- National Technology Transfer and Advancement Act (15 U.S.C. 272 note)
- Assessment of Federal Regulations and Policies on Families (Omnibus Appropriations Act 1999, Pub. L. 105-277 sec. 654 (1998))
- E.O. 12630, Government Actions and Interference with Constitutionally Protected Property Rights
- E.O. 12988, Civil Justice Reform
- E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks
- E.O. 13175, Consultation and Coordination with Indian Tribal Governments
- E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
- Program statutes, executive orders, and agency regulations or policies may impose other analytical requirements

Frequently Used Rulemaking Terms and Abbreviations

ANPRM	Advance Notice of Proposed Rulemaking	NegReg or RegNeg	Negotiated Rulemaking or Regulatory Negotiation
APA	Administrative Procedure Act	NPRM	Notice of Proposed Rulemaking
CFR	Code of Federal Regulations	OFR	Office of the Federal Register
CRA	Congressional Review Act	OIRA	Office of Information and Regulatory Affairs
DDH	Document Drafting Handbook	OMB	Office of Management and Budget
E.O.	Executive Order	PRA	Paperwork Reduction Act
FDMS	Federal Docket Management System	RFA	Regulatory Flexibility Act
FOIA	Freedom of Information Act	RFI	Request for Information
FR	*Federal Register*	RIA	Regulatory Impact Analysis/Assessment
GAO	Government Accountability Office	RIN	Regulation Identifier Number
IBR	Incorporation by Reference	SEISNOSE or SISNOSE	Significant economic impact on a substantial number of small entities
ICR	Information Collection Request	UMRA	Unfunded Mandates Reform Act
IFR	Interim Final Rule	U.S.C.	United States Code

Thank you!

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